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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,445	11/13/2001	A. Neil Barclay	DX 01052K1	1467

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EXAMINER	
QIAN, CELINE X	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,445	BARCLAY ET AL.	
	Examiner	Art Unit	
	Celine X. Qian Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 9-23 are pending in the application.

This Office Action is in response to the Amendment filed on 9/19/05.

Response to Amendment

The objection to claim 22 has been withdrawn in light of Applicant's amendment of the claim.

The rejection of claims 13 and 14 under 35 U.S.C. 112 2nd paragraph has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 9-23 under 35 U.S.C. 101/112 1st is maintained for reasons set forth of the record mailed on 6/30/05 and further discussed below.

The rejection of claims 9-23 under 35 U.S.C. 112 1st paragraph is maintained for reasons set forth of the record mailed on 6/30/05 and further discussed below.

Claim 11 is rejected under 35 U.S.C. 112 2nd paragraph for reason discussed below.

Response to Arguments

Claim Rejections - 35 USC § 101

Claims 9-23 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, substantial and specific asserted utility or a well established utility.

In response to this rejection, Applicants argue that the specification discloses a number of specific utilities for CD200R including functioning in specific conditions such as multiple sclerosis, rheumatoid arthritis, and autoimmune disease, thus the antibody to CD200R has utility as a therapeutic or a diagnostic agent. Applicants further argue that the disclosed utility is

substantial because treating or diagnosing diseases such as inflammation, multiple sclerosis, rheumatoid arthritis, and autoimmune disease is a real world use. Applicants also argue that the disclosed utility is credible because numerous publication demonstrating CD200R is involved in human disease. Further, Applicants argue that identification of a specific pathway is not required to demonstrate utility. Applicants assert that the disclosure of the specification, particularly page 75, lines 7-29, provides sufficient detail to meet the utility requirement, and a particular teaching that CD200R results in a particular disease is not required. Applicants cites MPEP 2107.02-03 to demonstrate that there is no legal requirement that the disclosed utility must be supported by conclusive experimental data, and applicant is only required to provide evidence if, when considered as a whole, leads the skilled artisan to conclude that the asserted utility is more likely than not true. Applicants thus conclude that the claimed invention has patentable utility.

The above arguments have been fully considered but deemed unpersuasive. The claims are rejected for same reasons as discussed in the previous office action mailed on 6/30/05. In response to Applicant's argument with regard to substantial, specific and credible uses, the examiner maintains the position that the specification fails to teach a substantial, specific and credible use for the claimed antibody or fragment. Although CD200 is known as a cell surface antigen identified in some specific cell type that are involved in inflammatory conditions, multiple sclerosis, rheumatoid arthritis, and autoimmune disease, the specification does not teach which specific disease is the result from the this particular CD200R. In other words, the specification does not teach which specific pathway in any specific cell type that leads to a specific disease. The list provided in the specification is based on the involvement of cells, for example, macrophages and dendritic cells, which are known to be involved in such diseases.

However, there is no teaching whether the involvement of such cells in those diseases is result from the expression of said CD200 antigen. Applicants are reminded that expression of a protein in certain cell type does not mean that said protein is responsible for all the activity of such cell type. Thus, the disclosure provided in the specification is a laundry list of the disease that are associated with the cells expressing said antigen, which does not provide a specific association between said diseases and CD200R. Although there is no legal requirement for Applicants to provide experimental data or establish a certain pathway for the involvement of CD200R and the listed of diseases disclosed on page 75, Applicants needs to provide at least some teaching or evidence for the relationship between the CD200R and the listed diseases. However, there is only the paragraph on page 75 which lists such diseases without further teaching of the relationship between CD200R and said diseases. Therefore, the specification fails to teach a specific, substantial and credible function to the CD200R. As such, the antibody to said receptor does not have specific, substantial and credible utility as well.

With regard to the cited art, all of them are post filing (which includes Cherwinski et al). As discussed previously, the teaching of the post filing art is not taught in the application, wherein the statue requires that the utility of the claimed invention is known at the time of filing. Moreover, none of reference establishes a direct relationship between the CD200R and the diseases that are alleged to result from the receptor dysfunction. With regard to Hoek et al., contrary to Applicant's assertion, this reference does not teach the relationship between the disease and the lack of the expression of CD200 is mediated through this specific CD200R. It is well known in the art many peptides may exert different effects through different pathways which is mediated through different receptors. There is no evidence suggest that this CD200R is

the only receptor which is responsible for the effect observed in the knockout mouse model as disclosed in Hoek et al. Whether the animal model disclosed in Gorczynki and Hoek et al. is accepted in the art has no relevance to demonstration of a direct relationship between CD200R and rhumatoid arthritis and multiple sclerosis. With regard to Foster-Cuvas, contrary to Applicant's assertion, the specification does not disclose the same teaching. The paragraph cited by Applicants is an example from the laundry list. Such teaching is not sufficient to support a credible, substantial and specific utility for CD200R encoded by SEQ ID NO:20. Similarly, the teaching provided in Cherwinski et al. (published on 9/25/03) is not taught in the specification either. Applicants' argument fails to address the point raised above. As such, Applicants fail to teach a credible, substantial and specific use for the claimed invention. Therefore, this rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-14 and 16-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to this rejection, Applicants argue that the specification provides adequate written description for the claimed CD200R-binding antibody and fragments. Applicants assert

that it is unclear why the examiner believes a compound that does not bind SEQ ID NO: 20 would fall within the scope of the claim. Applicants thus conclude that the written description requirement is satisfied.

The above argument has been fully considered. This rejection is withdrawn for claim 15 in view of the amendment because claim 15 is recites "the polypeptide of SEQ ID NO:20." However, the amended claim 9 read on an antibody or fragments which bind to a polypeptide consisting essentially of SEQ ID NO:20. Without definition from the specification, the claim language "consisting essentially of" in interpreted as "comprising." See MPEP 2111.03 R-3, "absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). As such, the rejection is maintained for same reasons as discussed in the previous office action. To clarify the position that the claimed antibody would read on an antibody or fragment that would bind to polypeptide other than SEQ ID NO:20, Applicants are reminded that the open claim language encompasses polypeptide include SEQ ID NO:20 but larger than SEQ ID NO:20 or fusion proteins (for example, claim 16). For example, an antibody to HA tag would bind to a polypeptide consist essentially of SEQ ID NO:20 and a HA tag, but not to the SEQ ID NO:20 itself. In view of the genus of the claimed invention, the specification fails to describe a representative number of species by their complete structure and

other identifying characteristics. Therefore, for reasons discussed in the previous office action and above, the written description requirement is not met, and this rejection is maintained.

Claims 9-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to this rejection, Applicants argue that the specification is sufficiently enabling to allow one skilled in the art to synthesize without undue experimentation the claimed invention. Applicants argue that the specification teaches the sequences of the antigen and the making the antibody with known sequence is well known in the art. Applicants thus conclude that the claimed invention is enabled.

The above arguments have been fully considered but deemed unpersuasive. The reasons for the non-enablement of the claimed invention is set forth in the previous office action. In addition to lack of utility of the claimed antibody (thus one would not know how to use it), Applicants are again reminded that 1) the claimed scope is not limited to antibody raise against SEQ ID NO:20 and fragments within (see discussion above). Although one skilled in the art would be able to make antibodies or fragments of the polypeptide which is not encompassed by SEQ ID NO:20 is unpredictable. Whether the skilled artisan can use the claimed binding compound according to the embodiments of the specification is also unpredictable (see lack of utility discussion). As such, the specification fails to provide enablement for how to make binding compound that are not antibody and how to use the claimed inventions. Therefore, this rejection is maintained.

New Grounds of Rejection Necessitated by Applicant's Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "the binding antibody or the antigen-binding fragment thereof is a Fv, Fab, or Fab2 fragment" renders the claim indefinite because an antibody is either an antibody or a fragment thereof, it cannot be both.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELIAN QIAN
PATENT EXAMINER